K040952

JUN 2 9 2004

510(k) Summary of Safety and Effectiveness
(As Required by 21 C.F.R. §807.92)

Applicant: Danville Materials, Inc.
2021 Omega Dr.
San Ramon, CA 94583

Contact Person: Craig R. Bruns
Phone 925 838-7940
Fax 925 838-0944
e-mail: cbruns@daneng.com

Date of summary March 12, 2004

Device name Prelude

Common name Agent, Tooth Bonding, Resin

Classification names	Regulation Number	Product Code
	21 CFR 872.3200	KLE

Device Description Prelude is a dental bonding agent used to restore all classes of cavities.

Predicate Device The device is substantially equivalent to other legally marketed devices in the United States including Optibond Solo Plus and Optibond Solo Plus 4 (K990498 & K014027), Clearfil SE (K990040) and Optibond Solo Plus Activator (K012082).

Intended Use Prelude is a light cured adhesive designed for direct restorations, i.e. composites and compomers to enamel and/or dentin, composite repairs, porcelain repairs and post and core build-up materials, and indirect restorations such as veneers, onlays, inlays, crowns and bridges. When used with Prelude Activator, Prelude may also be used with self or dual cure materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2004

Mr. Craig R. Bruns
President
Danville Materials, Inc.
2021 Omega Road
San Ramon, California 94583-1229

Re: K040952
Trade/Device Name: Prelude
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: June 23, 2004
Received: June 24, 2004

Dear Mr. Bruns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Pending~~ K040952

Device Name: Prelude

Indications For Use:

Prelude is a light cured adhesive designed for direct restorations, i.e. composites and compomers to enamel and/or dentin, composite repairs, porcelain repairs and post and core build-up materials, and indirect restorations such as veneers, onlays, inlays, crowns and bridges. When used with Prelude Activator, Prelude may also be used with self or dual cure materials.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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